Effective Date: 2/06/2024
Last Approval/Version: 02/2024
Next Review Due By: 02/2025
Policy Number: C27393-A

Abrysvo IL Medicaid Only

PRODUCTS AFFECTED

Abrysvo (respiratory syncytial virus vaccine)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Respiratory syncytial virus (RSV) prophylaxis in pregnancy

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

A. Prevention of respiratory syncytial virus (RSV):
   1. Member is 19 years of age or older
      [Molina Reviewer Note: Safety and efficacy of Abrysvo for individuals 50-59 years of age has not been established. Per HFS, prior authorization is not required for individuals 60 years of age and older.]
      AND
   2. Member has a documented diagnosis of pregnancy
      AND

3. Documented gestation between 32 to 36 weeks
   AND
4. Prescriber attests that the member has been informed of the benefits and risks

DURATION OF APPROVAL:
One vaccine (0.5 mL) per pregnancy term, limited to current RSV season

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
Adults 19-49 years of age

QUANTITY:
0.5 mL single dose

PLACE OF ADMINISTRATION:
The recommendation is that medications in this policy will be for pharmacy benefit coverage and administered by a healthcare professional qualified in vaccine administration.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intramuscular (IM) injection

DRUG CLASS:
Respiratory Syncytial Virus (RSV) Vaccine

FDA-APPROVED USES:
Abrysvo vaccine is indicated for:

1. Active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.
2. Active immunization for the prevention of LRTD caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. [**Molina Reviewer Note:** Prior authorization is not required for individuals 60 years of age and older, per Illinois HFS.]

Limitation of Use:
Concomitant administration of Tdap with Abrysvo in pregnant individuals has not been studied.
Safety and efficacy of Abrysvo for individuals 50-59 years of age has not been established.

COMPENDIAL APPROVED OFF-LABELED USES:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Respiratory syncytial virus (RSV) is recognized as one of the most common causes of childhood illness and is the most common cause of hospitalization in infants. It causes annual outbreaks of respiratory illnesses in all age groups. In most regions of the United States, RSV season starts in the fall and peaks in the winter, but the timing and severity of RSV season in a given community can vary from year to year.

Healthcare providers should consider RSV in the differential diagnosis of patients with respiratory illness, particularly during the RSV season. For more information about recommended infection prevention and control practices in healthcare settings, see CDC's 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

CDC recommends RSV vaccines to protect adults ages 60 and older from severe RSV, using shared clinical decision-making. To protect infants from severe RSV, CDC recommends an RSV vaccine for people who are 32–36 weeks pregnant or a monoclonal antibody given to the baby after birth. A healthcare provider's recommendation is one of the most important factors influencing a patient's choice to accept a new prevention product or vaccine.

Vaccines for Older Adults
New RSV vaccines are available for adults 60 and older. CDC recommends that adults 60 and older may receive a single dose of RSV vaccine, using shared clinical decision-making. The decision to vaccinate an individual patient should be based on a discussion between the healthcare provider and the patient. It may be informed by the patient's risk of severe RSV disease and their characteristics, values, and preferences; the healthcare provider's clinical discretion; and the characteristics of the vaccine.

Healthcare providers should be aware of underlying conditions that may increase the risk of severe RSV illness, and who might be most likely to benefit from these new vaccines.

RSV vaccine is recommended as a single dose. Studies are ongoing to determine whether (and if so, when) revaccination may be needed over time.

Immunizations to Protect Infants
Abrysvo is one of two safe and effective immunizations to prevent RSV lower respiratory tract infection in infants. Either a maternal vaccination or a monoclonal antibody is recommended, but administration of both is not needed for most infants.

Maternal Vaccines for Pregnant People
Abrysvo is a RSV vaccine is recommended for pregnant people who are 32–36 weeks pregnant with seasonal administration during September–January in most of the continental United States. In jurisdictions with seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climates), providers should follow state, local, or territorial guidance on timing of administration.

This vaccine provides protection against severe RSV illness to the recipient's baby for up to 6 months of age. However, the infant's protection will wane over time.

Healthcare providers of pregnant people should provide information on both maternal vaccines and infant monoclonal antibody products and consider patient preferences when determining whether to vaccinate the pregnant patient or to not vaccinate and rely on administration of nirsevimab to the infant after birth.

Clinical Description and Diagnosis in Infants and Young Children
RSV infection can cause a variety of respiratory illnesses and symptoms in infants and young children. It most commonly causes a cold-like illness but can also cause lower respiratory infections like bronchiolitis and pneumonia. Two to three percent of infants with RSV infection may need to be hospitalized. Severe disease most commonly occurs in very young infants. Additionally, children with any of the following underlying conditions are considered at increased risk:

- Premature infants
- Infants, especially those 6 months and younger
- Children younger than 2 years old with chronic lung disease or congenital heart disease
- Children with suppressed or weakened immune systems
- Children who have neuromuscular disorders or a congenital anomaly, including those who have difficulty swallowing or clearing mucus secretions

- Children with severe cystic fibrosis

Infants and young children with RSV infection may have rhinorrhea and a decrease in appetite before any other symptoms appear. Cough usually develops 1 to 3 days later. Soon after the cough develops, sneezing, fever, and wheezing may occur. Symptoms in very young infants can include irritability, decreased activity, and/or apnea.

Most otherwise healthy infants and young children who are infected with RSV do not need hospitalization. Those who are hospitalized may require oxygen, rehydration, and/or mechanical ventilation. Most improve with supportive care and are discharged in a few days.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

- All other uses of Abrysvo are considered experimental/investigational and therefore, will follow Molina's Off- Label policy.
- Contraindications to Abrysvo include: History of severe allergic reaction (e.g., anaphylaxis) to any component of Abrysvo.
- Potential risk of preterm birth. To avoid the potential risk of preterm birth with use of ABRYSVO before 32 weeks of gestation, administer ABRYSVO as indicated in pregnant individuals at 32 through 36 weeks gestational age.

OTHER SPECIAL CONSIDERATIONS:

Per Illinois HFS, prior authorization is not required (for any age) when Abrysvo is requested via the medical benefit. Members under 19 years of age can request Abrysvo through the Vaccines for Children (VFC) Program.

AVAILABLE DOSAGE FORMS

Abrysvo Solution for Injection 120MCG/0.5ML

REFERENCES

1. Illinois Medicaid Preferred Drug List, effective January 1, 2024
2. Abrysvo [prescribing information]. New York, NY: Pfizer Labs; August 2023.
3. Center for Disease Control and Prevention. Respiratory Syncytial Virus (RSV): Prophylaxis and high-risk groups. http://www.cdc.gov/rsv/clinical/index.html. Updated January 18, 2024. Accessed February 6, 2024

SUMMARY OF REVIEW/REVISIONS	DATE
New criteria creation	02/2024